

PCT

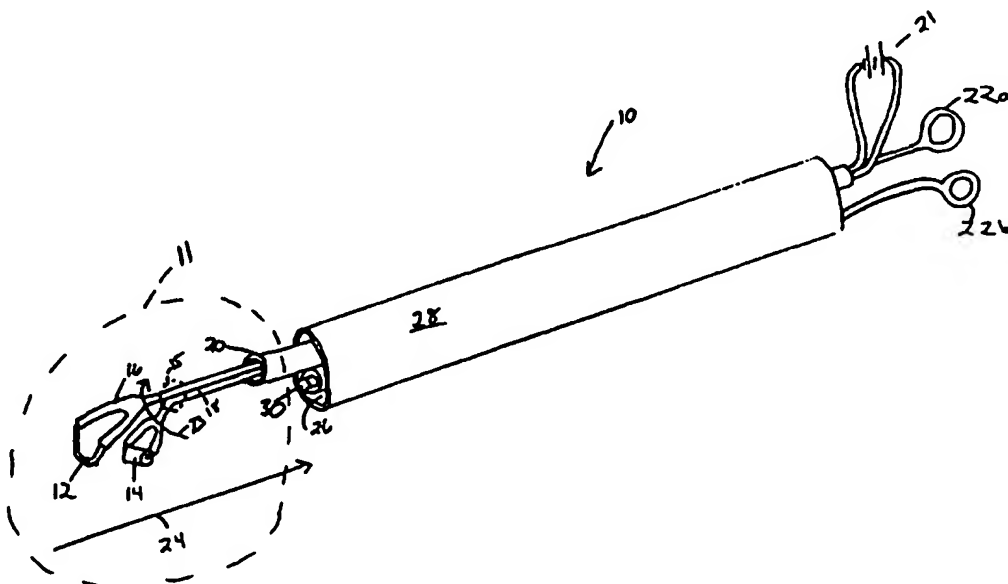
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/39		A1	(11) International Publication Number: WO 96/23449
			(43) International Publication Date: 8 August 1996 (08.08.96)
(21) International Application Number: PCT/US96/01331		(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) International Filing Date: 30 January 1996 (30.01.96)		Published With international search report.	
(30) Priority Data: 08/379,908 30 January 1995 (30.01.95) US 08/593,261 29 January 1996 (29.01.96) US			
(71) Applicant: BOSTON SCIENTIFIC CORPORATION [US/US]; One Boston Scientific Place, Natick, MA 01760-1537 (US).			
(72) Inventors: LENNOX, Charles, D. ; 17 Williams Drive, Hudson, MA 03051 (US). MORECI, Stephen, F. ; 22 Debbie Lane, Milford, MA 01757 (US).			
(74) Agents: FEIGENBAUM, David, F. et al. ; Fish & Richardson P.C., 225 Franklin Street, Boston, MA 02110 (US).			

(54) Title: ELECTRO-SURGICAL TISSUE REMOVAL



(57) Abstract

The invention features a bipolar electrosurgical apparatus having a first electrode (14) that has a relatively large surface area for creating a diffuse current sufficient to heat a region of tissue to coagulation temperatures, and a second electrode (12) that has a relatively small surface area for creating a concentrated current region sufficient to heat tissue adjacent to the second electrode (12) to resection temperatures. The first and second electrodes (12, 14) are relatively positioned along a treatment path, such that tissue is coagulated and resected as the electrosurgical apparatus is disposed along the path.

BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LJ	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

- 1 -

ELECTRO-SURGICAL TISSUE REMOVAL

Field of the Invention

This invention relates to electro-surgical tissue
5 removal.

Background

There are many medical procedures in which tissue
is cut or carved away. For example, a transurethral
resectioning of the prostate (TURP) is performed to treat
10 benign or cancerous prostatic hyperplasia. Transurethral
resectioning may also be performed in the bladder (TURB).
The obstructing tissue can be resected with an electro-
resectioning apparatus which is inserted into the urethra
through a resectoscope. An electric current heats the
15 tissue sufficiently to break intercellular bonds, cutting
the tissue into strips or "chips" which are removed from
the body through the resectoscope.

Extensive bleeding can occur as a result of
electro-resectioning, which can obstruct the physician's
20 view and lead to dangerous blood loss levels.
Additionally, veins have a negative pressure and may take
up ambient fluid when cut which can cause further
complications. The bleeding can be treated or avoided by
coagulating the tissue in the treatment area with an
25 electrocoagulator that applies a low level current to
denature cells to a sufficient depth without breaking
intercellular bonds.

Summary

In one aspect, the invention features a bipolar
30 electro-surgical apparatus having a first electrode that
has a relatively large surface area for creating a
diffuse current zone sufficient to heat a region of
tissue to coagulation temperatures and a second electrode
that has a relatively small surface area for creating a
35 concentrated current region sufficient to heat tissue
adjacent to the second electrode to resection

- 2 -

temperatures. The first and second electrodes are relatively positioned along a treatment path, such that tissue is coagulated and resected as the electro-surgical apparatus is disposed along the path.

5 Implementations of the invention may include the following features. The electrodes may be positioned such that coagulated tissue is resected as the apparatus is disposed along the treatment path, including positioning the first coagulating electrode proximally of
10 the second resecting electrode. The electrodes may be coupled to permit pivoting to vary the depth of treatment, for instance, the electrodes may be coupled at a cantilever joint, and the mounting for the second electrode may be stiffer than the mounting for the first
15 electrode. The apparatus may include a stop mechanism to limit the maximum depth of treatment. The electrodes may be substantially fixed to maintain their relative position along the treatment path, or they may be movable relative to each other along the treatment path. In
20 addition, the electrodes may be movable to opposite sides of each other along the treatment path. The first electrode may be a roller electrode or a sled electrode, and the second electrode may be a loop electrode. The electro-surgical apparatus may be constructed for use
25 with a resectoscope and may include a flow of fluid along at least one electrode surface for removing char.

In another aspect, the invention features a method for bipolar electro-surgical tissue removal. The method includes positioning a pair of bipolar electrodes along a
30 treatment path and imposing a voltage differential to cause current to flow through tissue between the electrodes. The method also includes diffusing the current at a first electrode to heat the tissue sufficiently to cause coagulation and concentrating the
35 current at a second electrode sufficiently to cause

- 3 -

resection of the tissue. Further, the method includes moving the first and second electrodes along the treatment path, such that the tissue is coagulated and resected.

5 Implementations of the invention may include the following features. The second electrode may be moved in a direction substantially perpendicular to the tissue surface to vary the depth of treatment. The electrodes may be pivoted. The first electrode may be moved
10 independent of the second electrode in an axial direction opposite to the direction of the treatment path and to an opposite side of the second electrode, and the electrodes may be moved along a new treatment path in the opposite direction, such that tissue is coagulated prior to being
15 resecting. The maximum depth of tissue resected by the second electrode may be limited.

 In another aspect, the invention features a bipolar electro-surgical apparatus including a roller electrode having a relatively large surface area for
20 creating a diffuse current region sufficient to heat tissue to coagulation temperatures to coagulate a region of tissue and a loop electrode having a relatively small surface area for creating a concentrated current region sufficient to heat tissue adjacent the loop electrode and
25 in the coagulation region to resection temperatures to resect the adjacent tissue. The roller electrode is positioned proximal to the loop electrode along a treatment path, such that tissue is coagulated prior to being resected to a desired depth as the device is moved
30 along the treatment path, and the roller electrode is connected to the loop electrode.

 In another aspect, the invention features a bipolar electro-surgical apparatus including a first electrode for coagulating tissue, and a second electrode
35 coupled to the first electrode for simultaneously

- 4 -

resecting tissue. When the resecting apparatus is moved along a treatment path, the second electrode resects tissue coagulated by the first electrode.

In another aspect, the invention features a
5 resectoscope including a bipolar electro-surgical device having a first electrode with a relatively smaller surface area for creating a concentrated current region sufficient to heat tissue adjacent the first electrode to resection temperatures and a second electrode with a
10 surface area which is larger than the surface area of the first electrode. The electrodes are positioned to coagulate and resect tissue adjacent to the electrodes as the electro-surgical device is moved along a treatment path.

15 In another aspect, the invention features a resectoscope including a bipolar electro-surgical device having a second electrode with a surface area which is slightly larger than the surface area of the first electrode, and the electrodes are positioned such that
20 current passing between the electrodes creates a more diffuse current zone sufficient to heat a region of tissue to coagulation temperatures and such that tissue is coagulated and resected as the electro-surgical device is moved along a treatment path.

25 Implementations of the invention may include the following features. The resectoscope may include a power connector electrically coupled to the electrodes, where the resectoscope is constructed for used with a monopolar electro-surgical device.

30 In another aspect, the invention features a resectoscope including a working channel configured to receive an electro-surgical device having bipolar electrodes and a power connector configured to electrically couple two conductors to the bipolar
35 electrodes.

- 5 -

Implementations of the invention may include the following features. The resectoscope may also include an electro-surgical device having bipolar electrodes, where a proximal portion of the electro-surgical device is
5 configured for insertion within the working channel and the bipolar electrodes are configured for electrical connection to the power connector. The bipolar electrodes may include a first electrode having a relatively small surface area and a second electrode
10 having a surface area which is slightly larger than the surface area of the first electrode. The bipolar electrodes may be loop electrodes.

In another aspect, the invention features an apparatus including a power connector adaptor configured
15 for use with a bipolar electro-surgical device and configured for use with a resectoscope that is configured for use with a monopolar electro-surgical device.

Implementations of the invention may include the following features. The apparatus may also include a
20 resectoscope configured for use with a monopolar electro-surgical device, and a bipolar electro-surgical device having bipolar electrodes, a proximal portion of the bipolar electro-surgical device configured to be inserted in a working channel of the resectoscope and the power
25 connector adaptor configured to electrically couple a power source to the bipolar electrodes of the bipolar electro-surgical device. The bipolar electrodes may be loop electrodes.

In another aspect, the invention features a method
30 for bipolar electro-surgical tissue removal including positioning a pair of bipolar electrodes along a treatment path in an ionic liquid environment and imposing a voltage differential to cause current to flow through tissue between the electrodes, where the current
35 flowing through the tissue is sufficient to heat and

- 6 -

cause coagulation of the tissue. The method further includes concentrating current at one of the bipolar electrodes, where the concentrated current is sufficient to resect tissue adjacent to the one of the bipolar
5 electrodes, and moving the electrodes along the treatment path to coagulate and resect tissue.

Implementations of the invention may include the following features. The ionic liquid environment may be saline.

10 In another aspect, the invention features similar methods for resecting tissue from a patient's prostate, e.g., transurethral resectioning procedure of the prostate, and for resecting tissue from a patient's bladder, e.g., transurethral resectioning of a patient's
15 bladder. Other similar methods include resecting tumors from walls of a patient's uterus, e.g., myomectomy, and resecting a portion of lining of a patient's uterus, e.g., endometrioma.

In another aspect, the invention features a method
20 for bipolar electro-surgical tissue removal including attaching a power connector adaptor to a resectoscope that is configured for use with a monopolar electro-surgical device and inserting a bipolar electro-surgical device having bipolar electrodes into a working channel
25 of the resectoscope, where the bipolar electro-surgical device is sized to fit within the working channel. The method further including electrically coupling the bipolar electrodes to the power connector adaptor.

Implementations of the invention may include the
30 following features. The method may include electrically connecting the power connector adaptor to a power source. The method may also include positioning the bipolar electrodes along a treatment path, imposing a voltage differential to cause current to flow through tissue
35 between the electrodes, where the current flowing through

- 7 -

the tissue is sufficient to heat and cause coagulation of the tissue, concentrating current at one of the bipolar electrodes, where the concentrated current is sufficient to resect tissue adjacent to the one of the bipolar
5 electrodes, and moving the electrodes along the treatment path, such that tissue is coagulated and resected. Before imposing a voltage differential, the method may include flushing the treatment path with an ionic fluid.

Embodiments of the invention may exhibit one or
10 more of the following advantages. Tissue can be coagulated just prior to resection in a single step operation to effect substantially bloodless tissue removal which can reduce complications from blood loss, fluid absorption, time in surgery, and patient trauma.
15 The operation can be carried out using a bipolar electro-surgical instrument that carries two, separate-function electrodes. One electrode concentrates current to cut tissue while the other diffuses the current to coagulate tissue. The electrodes are arranged along a line of
20 treatment such that tissue can be automatically, coagulated immediately before resection. The electrodes may also be positioned relative to each other in directions transverse to the direction of treatment so that the depth of cut and coagulation can be controlled
25 or preset, e.g., to prevent resection beyond the coagulation zone. Relatively high power, e.g., well above 60 watts, such as 100 watts or more, can be applied to effect deep tissue coagulation with low risk of injury to the patient because current is focused along a short
30 path between the bipolar electrodes. The instrument can be constructed for use with a variety of existing surgical devices and can be easily manufactured.

Tissue may be resected and coagulated substantially simultaneously in an ionic, non-osmotic
35 liquid environment, e.g., saline, to prevent

- 8 -

complications, e.g., electrolyte imbalance, caused by excessive fluid absorption. The operation can be carried out using a bipolar electro-surgical instrument that carries two substantially similar electrodes. Applying a
5 relatively high power, e.g., 150-300 Watts, to the electrodes causes current to pass and possibly an arc to form between the electrodes. One electrode is slightly smaller than the other electrode and concentrates current to cut tissue while the current passing between the two
10 electrodes coagulates tissue adjacent to the incision. The bipolar electro-surgical instrument may be sized to fit within an existing resectoscope that is designed for use with a monopolar electro-surgical instrument, and together with a power connector adaptor that electrically
15 couples the bipolar electrodes to a power source, an existing monopolar resectoscope is modified into a bipolar resectoscope.

Additional advantages and features are apparent from the following.

20 Detailed Description

Fig. 1a is a perspective view of an electro-surgical device positioned within a resectoscope.

Fig. 1b is a perspective view of the electro-surgical device of Fig. 1a.

25 Fig. 2 is an enlarged perspective view of a distal portion of the electro-surgical device of Fig. 1.

Fig. 3 is an enlarged top view of the distal portion of the electro-surgical device of Fig. 1.

Fig. 4 is an enlarged cross-sectional side view of
30 the distal portion of the electro-surgical device of Fig. 1.

Figs. 5-9 are cross-sectional side views of the distal portion of the electro-surgical device of Fig. 1a in use within a urethra.

- 9 -

Figs 10 and 11 are cross-sectional side-views illustrating structure and use of another embodiment of an electro-surgical device.

Fig. 12 is a side view of another resectoscope.

5 Fig. 13 is an exploded, side view of the resectoscope of Fig. 12.

Fig. 14 is an enlarged perspective view of a distal portion of an electro-surgical device of Fig. 12.

10 Fig. 15 is an enlarged side view of a power connector and a portion of a resectoscope handle.

Fig. 16 is an enlarged, side view, shown in partial cross-section, of the power connector of Fig. 15.

15 Figs. 17a-17c are cross-sectional side views of the electro-surgical device of Fig. 12 in use within a urethra.

Structure

Referring to Figs. 1-4, particularly to Figs. 1a and 1b, a transurethral resection assembly 10 includes a resectoscope 28 and a bipolar electro-surgical device 11
20 having a loop-form resecting electrode 12 and a coagulating electrode 14. When power is applied to the device, the larger surface area of coagulating electrode 14 diffuses current to coagulate tissue over a large region while the smaller surface area of resecting
25 electrode 12 concentrates current to resect immediately adjacent tissue. Since the coagulating electrode 14 is positioned ahead of the cutting electrode 12 along a line of resection 24, tissue is coagulated just prior to resection. Coagulating electrode 14 pivots (arrow 23)
30 with respect to resecting electrode 12 through cantilever joint region 15 which controls the depth of resection and coagulation.

Referring particularly to Figs. 2 and 3, the width W2 of mounting fork 46 of coagulating electrode 14 and
35 the width W1 of mounting fork 48 of resecting electrode

- 10 -

12 are substantially similar. As a result, mounting fork 48 engages mounting fork 46 to limit the maximum depth of resection to avoid resection of tissue beyond the coagulation zone, as will be described in more detail
5 below.

Resecting electrode 12 and coagulating electrode 14 are connected by wire leads that extend through electrical insulator jackets 16, 18, to a power source 21 (RF generator). The insulated leads extend in close
10 proximity through metal jacket 20 and are axially fixed relative to each other and jacket 20 by epoxy fill 17. Metal jacket 20 terminates proximally in articulation ring 22a. Ring 22b is connected (not shown) to resectoscope 28. Rings 22a and 22b are electrically
15 insulated from the electrodes and enable a physician to move metal jacket 20 and, hence, the electrodes within lumenal space 26 of resectoscope 28 in an axial direction along the resecting path 24.

The resectoscope also includes a telescope 30 that
20 images and illuminates resecting path 24. Telescope 30 is attached to metal jacket 20 through clip 32. As an alternative, separate lumens (i.e., one for metal jacket 20 and one for telescope 30) are provided within resectoscope 28. Additionally, lumenal space 26 is used
25 to irrigate and displace fluid (i.e., urine in the urethra) in the area of resection. Preferably, lumenal space 26 is filled with a non-osmotic, non-electrolytic, high impedance fluid such as glycine (not shown). The non-osmotic nature of glycine reduces damaging cellular
30 fluid absorption, and the non-electrolytic and high impedance nature of glycine insures that the current passed between the electrodes is focused in the tissue between the two electrodes.

To reduce the cost of the procedure, distilled
35 water (i.e., deionized water) can be used instead of

- 11 -

glycine. Like glycine, distilled water is non-electrolytic. However, unlike glycine, distilled water is osmotic. The substantially bloodless nature of the procedure, however, significantly reduces the amount of fluid absorbed by the patient. Hence, the osmotic nature of distilled water does not typically pose a danger.

In a particular embodiment, resecting electrode 12 is tungsten and coagulating electrode 14 is a silver/copper alloy, and the lead wires (not shown) within insulating jackets 16, 18, respectively, may be made of many materials, including brass, a copper alloy, or a silver alloy. Resecting electrode 12 has a loop-wire diameter d_1 of 0.012 inches (Fig. 4), a length L_1 of 0.30 inches (Fig. 2), and a height H of 0.325 inches (Fig. 2). Coagulating electrode 14 is a cylindrical roller with a diameter d_2 of about 0.125-0.187 inches (Fig. 4) and a length L_2 of between 0.187-0.25 inches (Fig. 2). Electrodes 12 and 14 are separated by a distance d_3 of approximately 0.187 inches (Fig. 4). Pivoting action of the electrodes can be facilitated by making the mounting fork 48 of resecting electrode 12 stiffer than the mounting fork of coagulating electrode 14, e.g., by using a stiffer wire within insulating jacket 18. Metal jacket 20 is made of stainless steel and has an outer diameter of about 0.068 inches, a wall thickness of about 0.005 inches, and an axial length of about 8.0 inches. The power source is a surgical radio frequency (RF) generator, generating a continuous sine wave (i.e., cut waveform) and operating at a typical frequency of 1MHz and at typical power levels of 100-300 Watts.

Use

Referring to Figs. 5-9, the operation of electro-surgical device 11 will be described with regard to a transurethral resectioning procedure (TURP). The

- 12 -

patient is prepared by inserting a resectoscope to the region of treatment. The physician, with a telescope and irrigation, inspects the region. The region is then flushed with glycine or distilled water.

5 Referring particularly to Fig. 5, the device 11 is inserted into the patient's urethra 40 through the resectoscope such that resecting electrode 12 and coagulating electrode 14 extend from resectoscope 28. When first inserted, cantilever joint 15 is fully open
10 such that coagulating electrode 14 rests on the surface of tissue to be resected and resecting electrode 12 is suspended a slight distance d_4 , approximately 0.040 inches, above the surface of the tissue to be resected. The separation is a safety factor since, if power is
15 accidentally applied, current will not pass between the electrodes in a glycine or distilled water environment until both electrodes contact the tissue surface.

Referring to Fig. 6, by applying an upward pressure to the external end of resectoscope 28, as
20 indicated by arrow 42, the physician pivots coagulating electrode 14 with respect to resecting electrode 12, as indicated by arrow 44. This pivoting brings resecting electrode 12 into contact with the tissue to be cut and brings the fork 46 (Fig. 2) of coagulating electrode 14
25 closer to the fork 48 of resecting electrode 12.

Once both electrodes are in contact with the surface of the tissue to be cut, the physician applies power to the electrodes through hand or foot controls (not shown). As discussed, both electrodes 12 and 14
30 must contact the tissue because the surrounding glycine or distilled water will not conduct current. Current 50 flows through the tissue between the two electrodes. The projected surface area (i.e., shadow or tissue contact area) of coagulating electrode 14 is about 2-5 times
35 larger than the projected surface area of resecting

- 13 -

electrode 12. As a result, the current density at resecting electrode 12 is larger than the current density at coagulating electrode 14. The larger surface area of coagulating electrode 14 disburses current over a wide, 5 deep area 29 and causes heating in the area sufficient only to coagulate the tissue (i.e., approximately 60 - 100°C). On the other hand, the small surface area of resecting electrode 12 concentrates the current density and causes heating in adjacent tissue sufficient to 10 resect the tissue. Typically, the heating induces a vigorous vaporization in the area immediately adjacent the electrode surface. (In some cases, a plasma arc may be generated in the area immediately adjacent the electrode with temperatures of approximately 1000°C and 15 above. However, lower temperatures, without arcing, can be used for resection.)

Referring to Fig. 7, when the physician increases the upward movement 42 of resectoscope 28, the electrodes pivot bringing electrically insulated forks 46, 48 in 20 contact and causing resecting electrode 12 to resect the tissue to its maximum depth M1 (Figs. 5 and 7). Since, the length L2 (Fig. 3) of coagulating electrode 14 is less than the width W1 of fork 48 the contact of both insulated forks limits the maximum depth of resection. 25 The maximum depth of resection is limited to prevent resection beyond the depth of coagulation. When forks 46, 48 are in contact, approximately half of coagulating electrode 14 extends between the tines of fork 48. The large surface area and low current density of coagulating 30 electrode 14 keeps coagulating electrode 14 from plunging into the tissue.

Approximately 100-300 Watts of power applied to the electrodes causes resecting electrode 12 to resect to a maximum depth M1 of about 0.20 inches (0.5 cm) and 35 coagulating electrode 14 to coagulate to a maximum depth

- 14 -

M2 of about 0.4 inches (1 cm). Coagulating 0.20 inches deeper than resection insures substantially bloodless resection.

Referring to Fig 8, the physician squeezes
5 articulation rings 22a and 22b together to pull the device 11 proximally. Coagulating electrode 14 rolls, as indicated by arrow 50, along resecting path 24 and resecting electrode 12 carves a chip 52 of tissue from urethra 40.

10 Referring to Fig. 9, in a typical transurethral procedure, the resecting path is from the bladder to the verumontanum in the prostate (approximately 1.5-10 inches). When the physician has reached the end of resection path 24 (i.e., the point where the physician
15 wishes to stop resecting), either stops applying upward pressure to resectoscope 28 allowing urethra 40 to cause resectoscope 28 to move in a downward direction, indicated by arrow 54, or directly applies a downward force to move the resectoscope in the downward direction.
20 This causes cantilever joint 15 to spring open, indicated by arrow 56, pivoting resecting electrode 12 upward and away from coagulating electrode 14. (Because coagulating electrode 14 travels ahead of resecting electrode 12 along the resecting path 24, a small portion of
25 coagulated tissue 58 remains in place (i.e., not resected).) During the procedure, the resected chips are normally kept in the patient's bladder, and once the resection is completed, the patient's bladder is evacuated making sure to remove all of the resected
30 chips.

Another Structure

Referring to Figs. 12-14, another transurethral resection assembly 100 includes a resectoscope 102 and a bipolar electro-surgical device 104 having two closely
35 spaced, substantially similar loop-form electrodes 106,

- 15 -

108. The thickness T1, approximately 0.027", of loop electrode 106 is slightly smaller than the thickness T2, approximately 0.030", of loop electrode 108. As a result, loop electrode 106 is the hot or cutting electrode while loop electrode 108 is the cold or return electrode. When power is applied to the device, loop electrode 106 concentrates the current density and causes heating in adjacent tissue sufficient to resect the tissue. The current 107 passing between the electrodes is dispersed over a region of tissue in the area of the incision and causes heating in the region sufficient only to coagulate the tissue in the region. By applying excessive power, approximately 125-300 Watts, to the electrodes, the tissue in the area of the incision may be coagulated to a depth sufficient to minimize or eliminate bleeding.

Spacing two substantially similar loop electrodes a small distance d5, e.g., 0.027", apart provides a low impedance path between the loop electrodes and insures that the current passing between the loop electrodes is confined to a short path. Confining the current path permits safe high power, e.g., 125-300 Watts, electro-surgery. Additionally, the electrodes are capable of resecting tissue in a conductive liquid environment, e.g., saline, because the current is focused in the tissue between the electrodes and is not disbursed through the conductive liquid.

Although coagulating tissue before or substantially simultaneously with tissue resectioning reduces fluid absorption via venous sinus, fluid absorption may still occur. For example, in a myomectomy procedure a tumor is resected from the uterus wall. Prior to tissue resectioning, the uterus is pressure distended with fluid which significantly increases the likelihood of excessive fluid absorption. Excessive

- 16 -

absorption of non-ionic fluids such as glycine can lead to life threatening electrolyte imbalance. Resecting tissue in an ionic liquid environment such as saline reduces the risk of electrolyte imbalance.

5 Loop electrodes 106, 108 are connected by wire leads that extend through electrical insulator jackets 110, 112 to electrical contact ring 114 and electrical contact pin 116, respectively. The insulated leads are axially fixed in parallel relative to each other. Ring
10 114 and pin 116 are electrically coupled with banana plugs 120, 122, respectively, through a power connector 118. During operation, the banana plugs are connected to an RF generator (not shown).

 Pin 116 is inserted through a distal end 123 of a
15 metal jacket 124 in resectoscope 102 and into an aperture 125 (Figs. 15 and 16) in power connector 118. The power connector includes a knife edge lock 129 for grasping pin 116 and electrically connecting to pin 116 and a leaf spring connector 131 for grasping ring 114 and
20 electrically connecting to ring 114. The resectoscope includes a push-button release mechanism 133 that operates through an aperture 135 in the power connector to release pin 116 from lock 129.

 An O-ring or a silicone membrane (i.e., diaphragm
25 or septum) 200 (Fig. 16) is placed at the opening 202 of aperture 125 in power connector 118 to prevent liquid from entering the power connector and forming a conductive path between pin 116 and ring 114. Pin 116 is passed through the O-ring, diaphragm, or septum when the
30 bipolar electro-surgical device is inserted within the power connector.

 After a procedure is complete and the resectoscope is removed from the patient, electro-surgical device 104 is removed from the resectoscope using the push-button
35 release and may be thrown away or cleaned. Prior to the

- 17 -

next procedure, a physician may insert a new or cleaned electro-surgical device 104 within the resectoscope.

Use

Referring to Figs. 17a-17c, the operation of
5 electro-surgical device 104 will be described with regard to a transurethral resectioning procedure (TURP). The patient is prepared by inserting a bullet-nosed obturator (not shown) within a sheath 101 (Fig. 13) to the region of treatment. The obturator is then removed from the
10 sheath while leaving the sheath within the patient, and a resectoscope and bipolar electro-surgical device assembly is then inserted into the sheath. The assembly includes a telescope 160 that is inserted through rail 134 and a metal jacket 162 (Fig. 13) of resectoscope 102. With
15 telescope 160 and irrigation, the physician inspects the region. The region is then flushed with saline.

Resectoscope 102 includes a two-piece handle having a proximal thumb piece 126a and a distal finger piece 126b. Power connector 118 is attached to thumb
20 piece 126a. A physician inserts his thumb through ring 128 in thumb piece 126a and lays his fingers across indentations 130a, 130b, 130c in finger piece 126b and squeezes to slide (arrow 132, Fig. 17a) the thumb piece along rails 134, 136 against a force (arrow 138) provided
25 by a spring 140. Sliding the thumb piece toward the finger piece pushes bipolar electro-surgical device 104 through metal jacket 124 in the resectoscope to cause electrodes 106, 108 to extend away from (arrow 142) distal end 123 (Fig. 13) of resectoscope 102 and a distal
30 end 146 of sheath 101.

The physician applies power to the loop electrodes by turning on the RF generator and applies an upward pressure to the external end of resectoscope 102, as indicated by arrow 147, to bring the electrodes in
35 contact with tissue 155. The physician then slowly

- 18 -

releases his grip on the two-piece handle to allow the thumb piece to move away from (arrow 148, Fig. 17c) the finger piece and the electrodes to move back toward (arrow 150) the distal end of the sheath. As the
5 electrodes are moved back toward the sheath, cutting electrode 106 resects a chip 152 of tissue from a resecting path 154 within the patient's urethra 156, and current 154 passing between the electrodes coagulates tissue in the area 157 of the incision. When the thumb
10 piece of the handle is completely released, the electrodes are pulled back into the sheath and chip 152 is cut off against a lower portion 158 of the distal end of the sheath. The physician then either stops applying upward pressure to resectoscope 102 allowing urethra 156
15 to cause the resectoscope to move in a downward direction, indicated by arrow 159, or directly applies a downward force to move the resectoscope in the downward direction.

Other Embodiments

20 Many additional embodiments are possible. For example, referring again to Figs. 15 and 16, power connector 118 may be an adaptor power connector that is attached to a resectoscope designed for use with a monopolar electro-surgical device to allow a physician to
25 perform bipolar electro-surgery. The adaptor power connector may be an insert molded part. The slide distance d6 (Fig. 17a) is equal to the distance d7 which the loop electrodes may be extended from the distal end of the sheath. The width W3 of the adaptor power
30 connector is minimized to avoid decreasing the slide distance.

As another example, the length L2 of coagulating electrode 14 (Fig. 2) can be cut with grooves (not shown) to increase the traction coagulating electrode 14 has
35 with the tissue surface. Similarly, the surface of

- 19 -

coagulating electrode 14 can be polished to prevent debris from sticking to coagulating electrode 14. Instead of using a roller electrode for coagulation, a sled electrode (i.e., does not roll, not shown) with the same surface area could be used. Coagulating electrode 14 is preferred, however, because as coagulating electrode 14 rolls (i.e., turns in direction 50) it prevents the build up of debris along resecting path 24.

In other embodiments, a fluid flow directly over the electrodes may be provided to wash away char that could interfere with current flow. The flow could be provided by, for example, a small tube running through metal jacket 20 that terminates in a nozzle-form directed onto the electrode surfaces. In another example, the electrode and electrode lead could be hollow allowing fluid to flow and the working surface perforated such that fluid weeps from the electrode to wash away char. The fluid may be saline or another conductive fluid that does not inhibit current flow. Washing fluid flow can be initiated and terminated by a foot pedal, which may be the same foot pedal that turns on power.

Referring to Figs. 10 and 11, to avoid leaving excess coagulated tissue region 58 in place at the end of a cut, electrodes 12 and 14 can be configured to move in an axial direction (i.e., along resection path 24) independent of each other. This axial action can be achieved by passing the insulated leads to the resecting and coagulation electrodes through sperate lumens within sheath 20. When the physician reaches the end of resection path 24, the physician uses a mechanism to independently push coagulating electrode 14 back along resecting path 24 in an axial direction, indicated by arrow 60, until coagulating electrode 14 is on an opposite side of resecting electrode 12. As a result,

- 20 -

coagulated tissue region 58 is removed as part of chip 52.

In order to move coagulating electrode 14 to an opposite side of resecting electrode 12, the width W2 (Fig. 2) of coagulating electrode 14 fork 46 is much smaller than the width W1 of resecting electrode 12 fork 48. Additionally, to prevent the two electrodes from coming in contact with each other, the length L2 of coagulating electrode 14 is made less than the length L1 of resecting electrode 12.

Allowing electrodes 12 and 14 to move in an axial direction independent of each other can also be used to change the direction of resection. Urging coagulating electrode 14 to an opposite side of resecting electrode 12 allows for coagulation and resection along a resecting path in a direction opposite to resecting path 24. Because a physician will normally carve several chips out of the urethra in a transurethral procedure, by changing the direction of the resecting path, the physician carves a chip out with each push and then with each pull of the device.

The electrodes may also include a flushing apparatus to remove char. A tube 70, extending from outside the device, terminates in a nozzle 72 that directs a flow of saline onto the roller. The resecting electrode is a hollow-form with perforations 74 through which saline can weep onto the working surface.

Coupling and pivoting mechanisms, other than the fork 46, 48 arrangement, can be employed. The maximum depth of resection may not be limited by a stop engagement. The resecting electrode can be constructed such that the coagulation electrode can pass beyond the mounting for the resecting electrode. If the width of the fork of the coagulating electrode is less than the width between the two loop halves of the resecting

- 21 -

electrode, the depth of resection is not limited. Using the telescope 30, the physician can manually control the maximum depth of resection. Coagulation may be carried out just after resection, by reversing the orientation of the electrodes.

The electro-surgical devices can be constructed for use in various procedures, including endoscopic, laparoscopic (i.e., the electrode configuration extends through a trocar), and cystoscopic procedures. The device can have a flexible shaft for delivery deep into the body. The devices can be configured for removal or debulking of tumors in, e.g., the esophagus, cervix, or uterus (myomectomy), or for removal of liver lobe sections or removal of any protruding vascular tissue. The devices may also be configured to resect the lining of the uterus (endometrioma) or for use in transurethral resectioning of the bladder (TURB).

The devices can be constructed to carry multiple different resecting and/or coagulating electrodes among which power can be switched to vary the depth or width of treatment. For example, the device may carry two resecting loops arranged and of different size to allow cutting to different maximum depths. Differently shaped coagulating electrodes can be carried to vary the coagulation pattern. By switching among the different electrodes, the physician can tailor the treatment without removing the device from the body. The different electrodes can be arranged in parallel about or in series along the device axis. The power applied to the device can be varied with device construction and purpose (tissue type). Small scale devices, e.g., for use in the brain, may use lower power settings, e.g., 10 Watts. The arrangement can be adapted for a handheld device for use in open surgery. Moreover, the resecting electrode can be replaced with a different shaped small surface area

- 22 -

resecting electrode, and the coagulating electrode can be replaced with a different shaped larger surface area coagulating electrode.

Other embodiments are within the following claims.

- 23 -

What is claimed is:

1. A resectoscope comprising:

a bipolar electro-surgical device comprising:

5 a first electrode having a relatively smaller surface area for creating a concentrated current region sufficient to heat tissue adjacent the first electrode to resection temperatures; and

a second electrode having a surface area which is larger than the surface area of the first electrode;

10 the electrodes being positioned to coagulate and resect tissue adjacent to the electrodes as the electro-surgical device is moved along a treatment path.

2. A resectoscope comprising:

a bipolar electro-surgical device comprising:

15 a first electrode having a relatively smaller surface area for creating a more concentrated current region sufficient to heat tissue adjacent the first electrode to resection temperatures; and

20 a second electrode having a surface area which is slightly larger than the surface area of the first electrode;

the electrodes being positioned such that current passing between the electrodes creates a more diffuse current zone sufficient to heat a region of tissue to coagulation temperatures and such that tissue is coagulated and resected as the electro-surgical device is moved along a treatment path.

3. The resectoscope of claim 2 further comprising:

30 a power connector adaptor electrically coupled to the electrodes, wherein the resectoscope is constructed for use with a monopolar electro-surgical device.

4. A resectoscope comprising:

a working channel configured to receive an electro-surgical device having bipolar electrodes; and

35

- 24 -

a power connector configured to electrically couple two conductors to the bipolar electrodes.

5. The resectoscope of claim 4, further comprising:

5 an electro-surgical device having bipolar electrodes, a proximal portion of the electro-surgical device being configured for insertion within the working channel and the bipolar electrodes being configured for electrical connection to the power connector.

10 6. The resectoscope of claim 5, wherein the bipolar electrodes include:

a first electrode having a relatively small surface area for creating a more concentrated current region sufficient to heat tissue adjacent the first
15 electrode to resection temperatures; and

a second electrode having a surface area which is slightly larger than the surface area of the first electrode;

the electrodes being relatively positioned along a
20 treatment path such that current passing between the electrodes creates a more diffuse current zone sufficient to heat a region of tissue to coagulation temperatures and such that tissue is coagulated and resected as the resectoscope is disposed along the treatment path.

25 7. The resectoscope of claim 6, wherein the bipolar electrodes are loop electrodes.

8. An apparatus comprising:

a power connector adaptor configured for use with a bipolar electro-surgical device and configured for use
30 with a resectoscope that is configured for use with a monopolar electro-surgical device.

9. The apparatus of claim 8, further comprising:

a resectoscope configured for use with a monopolar electro-surgical device, and

- 25 -

a bipolar electro-surgical device having bipolar electrodes, a proximal portion of the bipolar electro-surgical device being configured for insertion in a working channel of the resectoscope and the power
5 connector adaptor being configured to electrically couple a power source to the bipolar electrodes of the bipolar electro-surgical device.

10. The apparatus of claim 8, wherein the bipolar electrodes are loop electrodes.

10 11. A method for bipolar electro-surgical tissue removal, comprising:

positioning a pair of bipolar electrodes along a treatment path in an ionic liquid environment;

15 imposing a voltage differential to cause current to flow through tissue between the electrodes, the current flowing through the tissue being sufficient to heat and cause coagulation of the tissue;

concentrating current at one of the bipolar electrodes, the concentrated current being sufficient to
20 resect tissue adjacent to the one of the bipolar electrodes; and

moving the electrodes along the treatment path, such that tissue is coagulated and resected.

12. The method of claim 11, wherein the ionic
25 liquid environment is saline.

13. A method of resecting tissue from a patient's prostate comprising:

positioning a pair of bipolar electrodes along a treatment path with the patient's urethra;

30 flushing the treatment path with an ionic fluid;

imposing a voltage differential to cause current to flow through tissue between the electrodes, the current flowing through the tissue being sufficient to heat and cause coagulation of the tissue;

- 26 -

concentrating current at one of the bipolar electrodes, the concentrated current being sufficient to resect tissue adjacent to the one of the bipolar electrodes; and

5 moving the electrodes along the treatment path, such that tissue is coagulated and resected from the patient's urethra.

14. The method of claim 13, wherein the method of resecting tissue from a patient's prostate comprises a
10 transurethral resectioning procedure.

15. A method of resecting tissue from a patient's bladder comprising:

positioning a pair of bipolar electrodes along a treatment path with the patient's bladder;

15 distending the patient's bladder with an ionic fluid;

imposing a voltage differential to cause current to flow through tissue between the electrodes, the current flowing through the tissue being sufficient to
20 heat and cause coagulation of the tissue;

concentrating current at one of the bipolar electrodes, the concentrated current being sufficient to resect tissue adjacent to the one of the bipolar electrodes; and

25 moving the electrodes along the treatment path, such that tissue is coagulated and resected from the patient's bladder.

16. The method of claim 15, wherein the method of resecting tissue from a patient's bladder comprises a
30 transurethral resectioning procedure.

17. A method of resecting tumors from walls of a patient's uterus comprising:

positioning a pair of bipolar electrodes along a treatment path with the patient's uterus;

- 27 -

distending the patient's uterus with an ionic fluid;

imposing a voltage differential to cause current to flow through tissue between the electrodes, the
5 current flowing through the tissue being sufficient to heat and cause coagulation of the tissue;

concentrating current at one of the bipolar electrodes, the concentrated current being sufficient to resect tissue adjacent to the one of the bipolar
10 electrodes; and

moving the electrodes along the treatment path, such that tissue is coagulated and resected from a patient's uterus.

18. The method of claim 17, wherein the method of
15 resecting tumors from walls of a patient's uterus comprises a myomectomy procedure.

19. A method of resecting a portion of lining of a patient's uterus comprising:

positioning a pair of bipolar electrodes along a
20 treatment path with the patient's uterus;

distending the patient's uterus with an ionic fluid;

imposing a voltage differential to cause current to flow through a portion of the lining between the
25 electrodes, the current flowing through the portion of the lining being sufficient to heat and cause coagulation of the portion;

concentrating current at one of the bipolar electrodes, the concentrated current being sufficient to
30 resect a portion of the lining adjacent to the one of the bipolar electrodes; and

moving the electrodes along the treatment path, such that a portion of the lining is coagulated and resected from a patient's uterus.

- 28 -

20. The method of claim 19, wherein the method of resecting a portion of lining of a patient's uterus comprises an endometrioma procedure.

21. A method for bipolar electro-surgical tissue
5 removal, comprising:

attaching a power connector adaptor to a
resectoscope that is configured for use with a monopolar
electro-surgical device;

inserting a bipolar electro-surgical device having
10 bipolar electrodes into a working channel of the
resectoscope, the bipolar electro-surgical device being
sized to fit within the working channel; and

electrically coupling the bipolar electrodes to
the power connector adaptor.

15 22. The method of claim 21, further comprising:
electrically connecting the power connector
adaptor to a power source.

23. The method of claim 21, further comprising:
positioning the bipolar electrodes along a
20 treatment path;

imposing a voltage differential to cause current
to flow through tissue between the electrodes, the
current flowing through the tissue being sufficient to
heat and cause coagulation of the tissue;

25 concentrating current at one of the bipolar
electrodes, the concentrated current being sufficient to
resect tissue adjacent to the one of the bipolar
electrodes; and

moving the electrodes along the treatment path,
30 such that tissue is coagulated and resected.

24. The method of claim 23 further comprising,
before imposing a voltage differential:

flushing the treatment path with an ionic fluid.

25. A bipolar electro-surgical apparatus,
35 comprising:

- 29 -

a first electrode having a relatively large surface area for creating a diffuse current zone sufficient to heat a region of tissue to coagulation temperatures; and

5 a second electrode having a relatively small surface area for creating a concentrated current region sufficient to heat tissue adjacent said second electrode to resection temperatures;

said electrodes being relatively positioned along
10 a treatment path such that tissue is coagulated and resected as said electro-surgical apparatus is disposed along said path.

26. The electro-surgical apparatus of claim 25 wherein said electrodes are positioned such that
15 coagulated tissue is resected as said apparatus is disposed along said treatment path.

27. The electro-surgical apparatus of claim 26 wherein said first coagulating electrode is positioned proximally of said second resecting electrode such that
20 tissue is coagulated just prior to resection.

28. The electro-surgical apparatus of claim 25 wherein said first said second electrodes are coupled to permit pivoting to vary the depth of treatment.

29. The electro-surgical apparatus of claim 28,
25 wherein said electrodes are coupled at a cantilever joint.

30. The electro-surgical apparatus of claim 29, wherein said mounting for said second electrode is stiffer than said mounting for said first electrode.

30 31. The electro-surgical assembly of claim 28 or 29 including a stop mechanism to limit the maximum depth of treatment.

32. The electro-surgical apparatus of claim 25 wherein said first and second electrodes are

- 30 -

substantially fixed to maintain the position along said path.

33. The electro-surgical apparatus of claim 25 wherein said first and second electrodes are
5 movable relative to each other along said treatment path.

34. The electro-surgical apparatus of claim 33, wherein said first and second electrodes are movable to opposite sides of each other along said path.

35. The electro-surgical apparatus of claim 25,
10 wherein said first electrode is a roller electrode.

36. The electro-surgical apparatus of claim 25, wherein said first electrode is a sled electrode.

37. The electro-surgical apparatus of claim 25, wherein said second electrode is a loop electrode.

15 38. The electro-surgical apparatus of claim 25, wherein said electro-surgical apparatus is constructed for use with a resectoscope.

39. The electro-surgical apparatus of claim 25 including a flow of fluid along at least one electrode
20 surface for removing char.

40. A method for bipolar electro-surgical tissue removal, comprising:

positioning a pair of bipolar electrodes along a treatment path,

25 imposing a voltage differential to cause current to flow through tissue between said electrodes,

diffusing said current at a first electrode to heat said tissue sufficiently to cause coagulation,

concentrating said current at a second electrode
30 sufficiently to cause resection of said tissue, and
moving said first and second electrodes along said treatment path, such that said tissue is coagulated and resected.

41. The method of claim 40, including:

- 31 -

moving said second electrode in a direction substantially perpendicular to said tissue surface to vary the depth of treatment.

42. The method of claim 41, including:
5 pivoting said electrodes.

43. The method of claim 40, including:
moving said first electrode, independent of said second electrode, in an axial direction opposite to the direction of said treatment path and to an opposite side
10 of said second electrode.

44. The method of claim 43, further including:
moving said first and second electrodes along a new treatment path in said opposite direction, such that tissue is coagulated prior to being resecting.

45. The method of claim 40, further including:
15 limiting the maximum depth of tissue resection by said second electrode.

46. A bipolar electro-surgical apparatus,
comprising:

20 a roller electrode having a relatively large surface area for creating a diffuse current region sufficient to heat tissue to coagulation temperatures to coagulate a region of tissue;

a loop electrode having a relatively small surface
25 area for creating a concentrated current region sufficient to heat tissue adjacent said loop electrode and in said coagulation region to resection temperatures to resect said adjacent tissue;

said roller electrode being positioned proximal to
30 said loop electrode along a treatment path, such that tissue is coagulated prior to being resected to a desired depth as said device is moved along said treatment path;
and

said roller electrode being connected to said loop
35 electrode.

- 32 -

47. A bipolar electro-surgical apparatus,
comprising:

a first electrode for coagulating tissue; and a
second electrode coupled to said first electrode for
5 simultaneously resecting tissue, wherein when the
resecting apparatus is moved along a treatment path, said
second electrode resects tissue coagulated by said first
electrode.

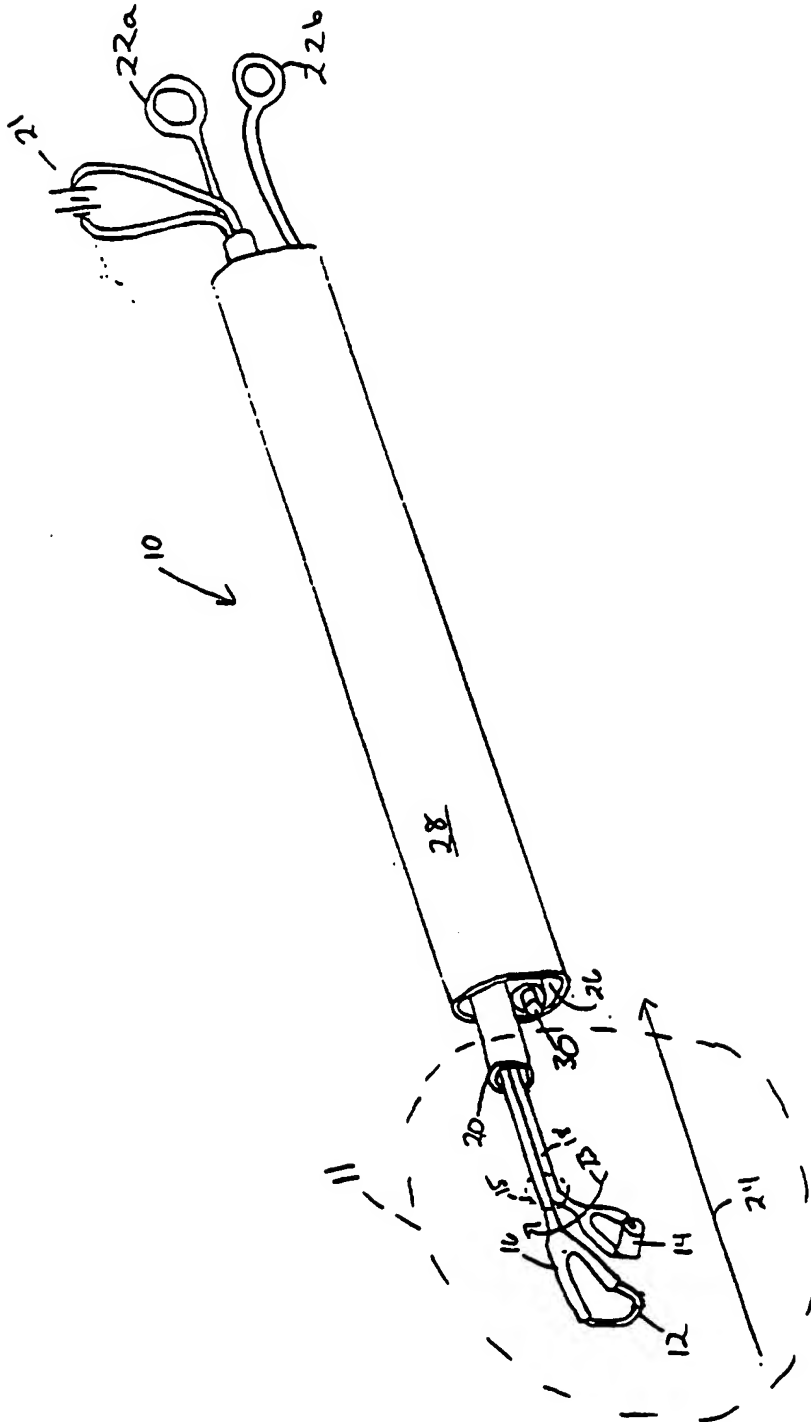


FIG. 1a

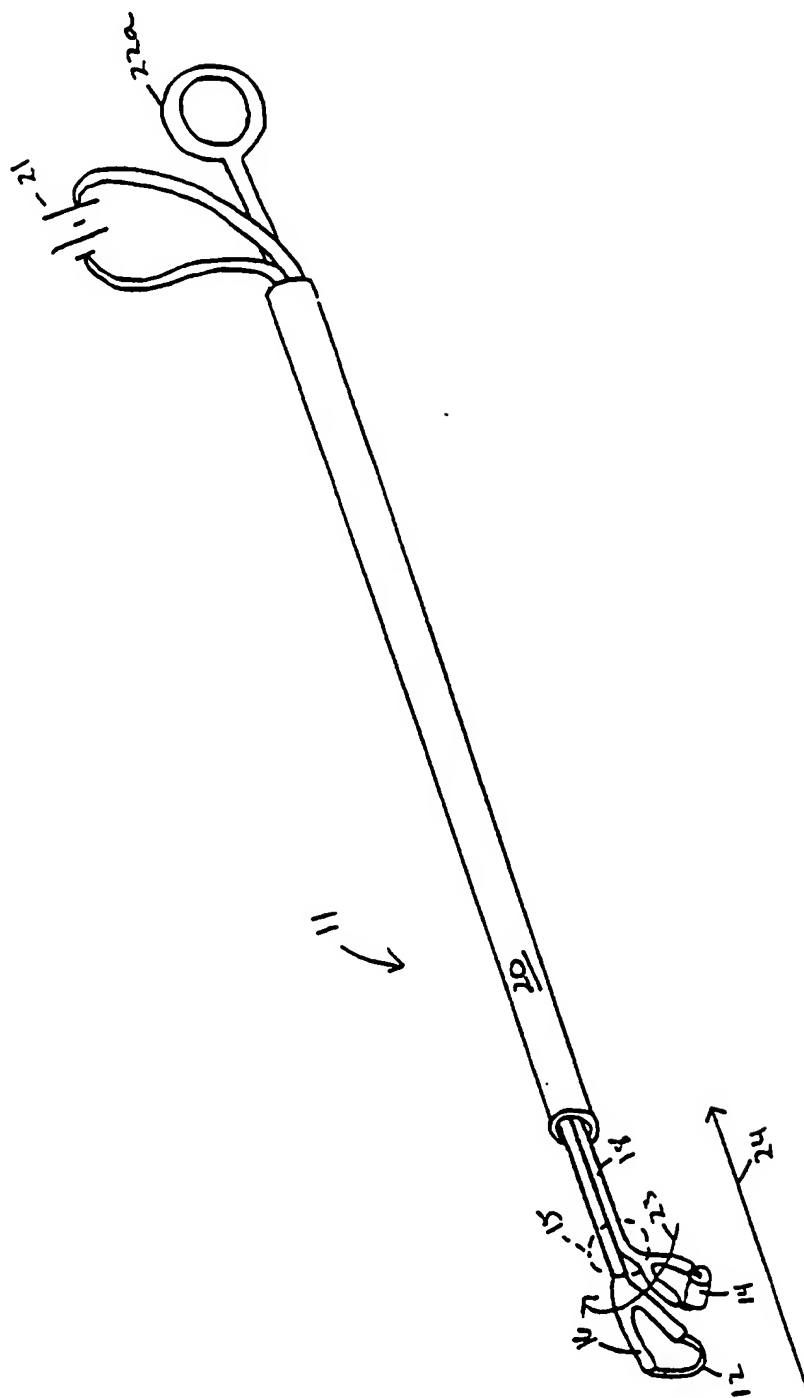


FIG. 16

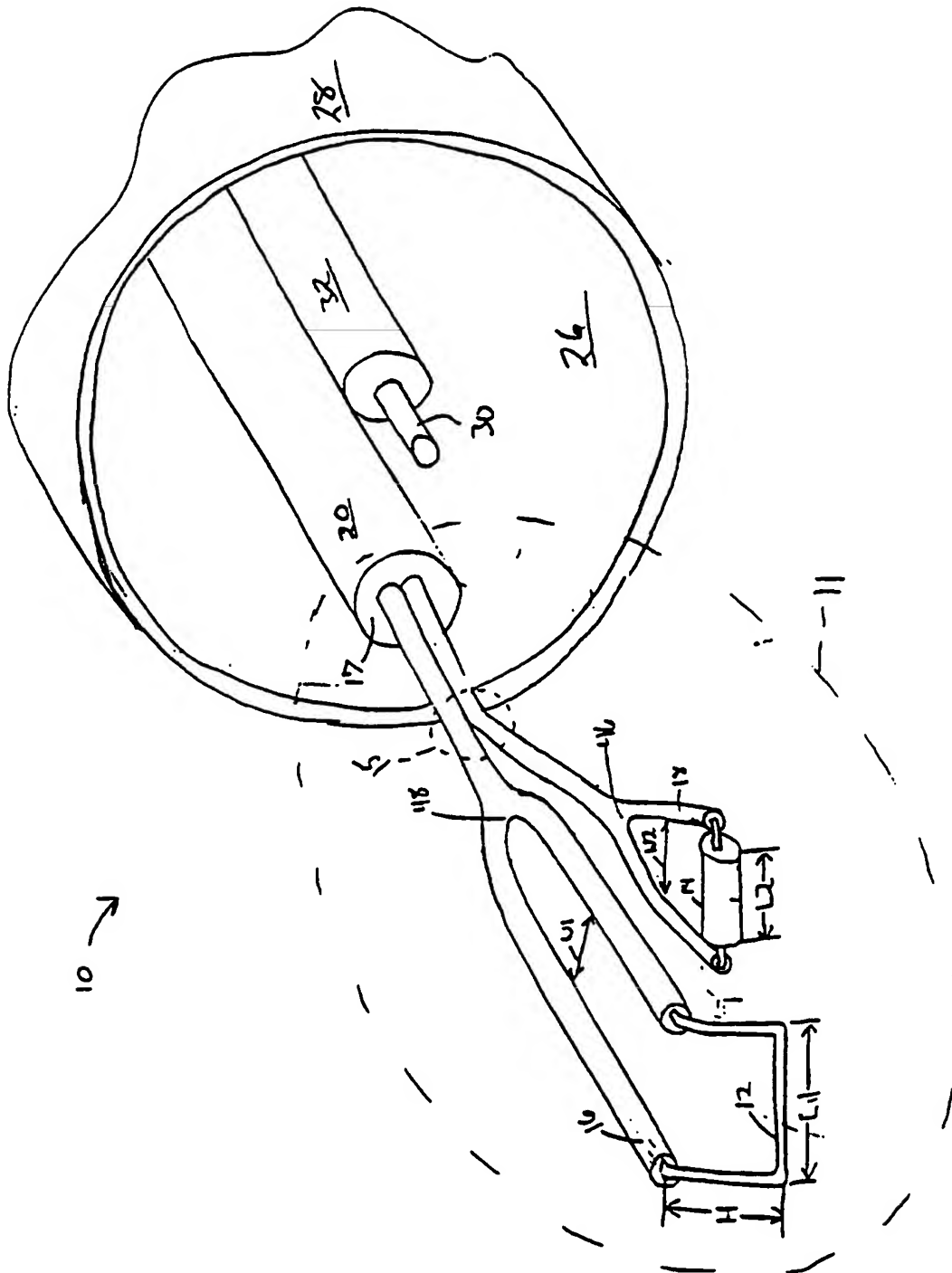


FIG. 2

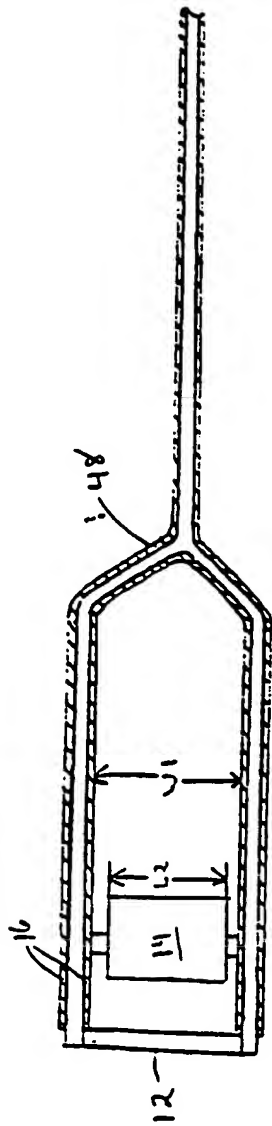
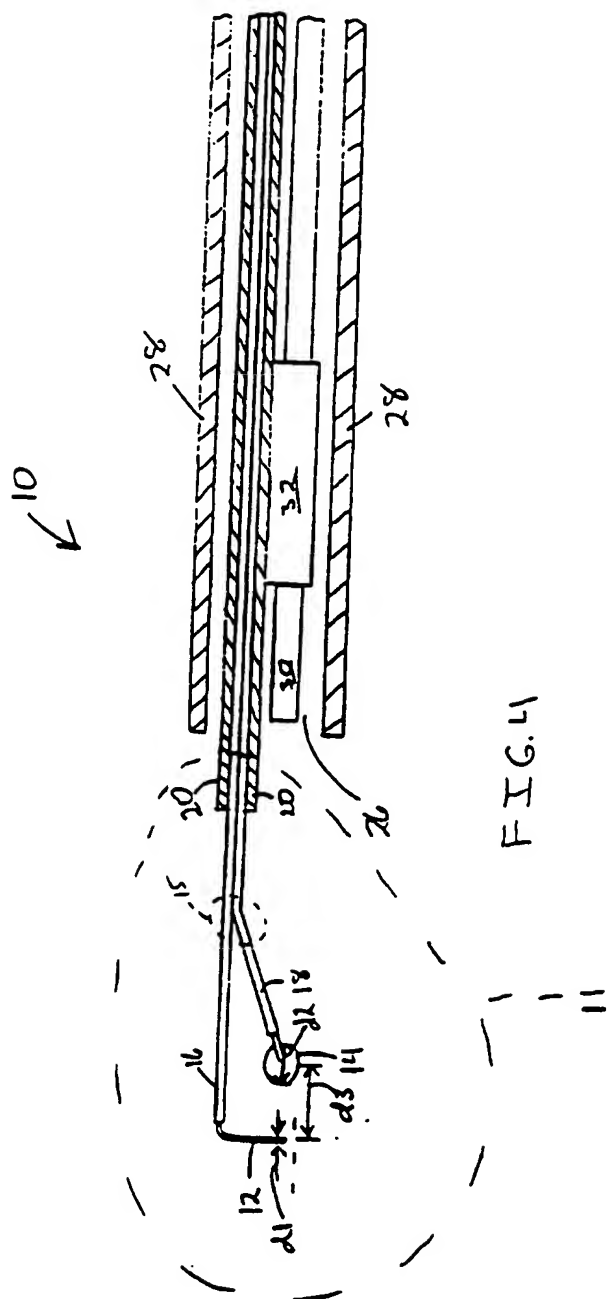


FIG. 3

05 / 15



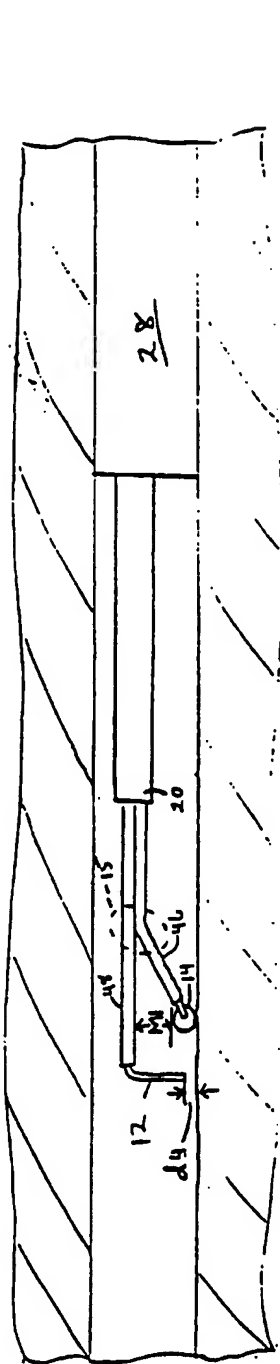


FIG. 5

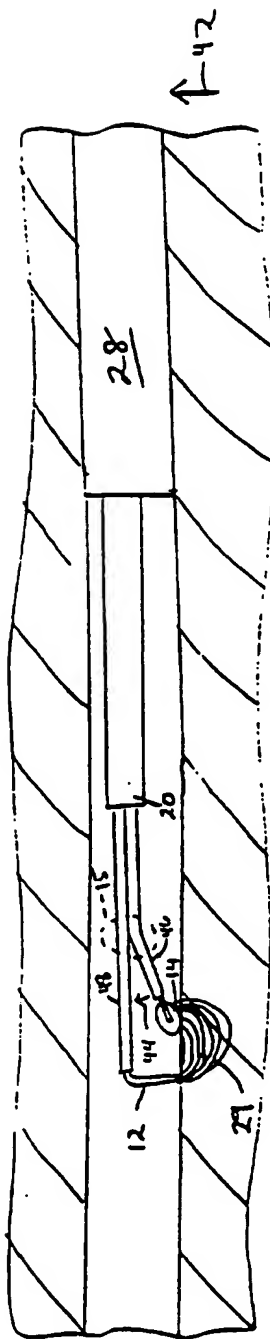


FIG. 6

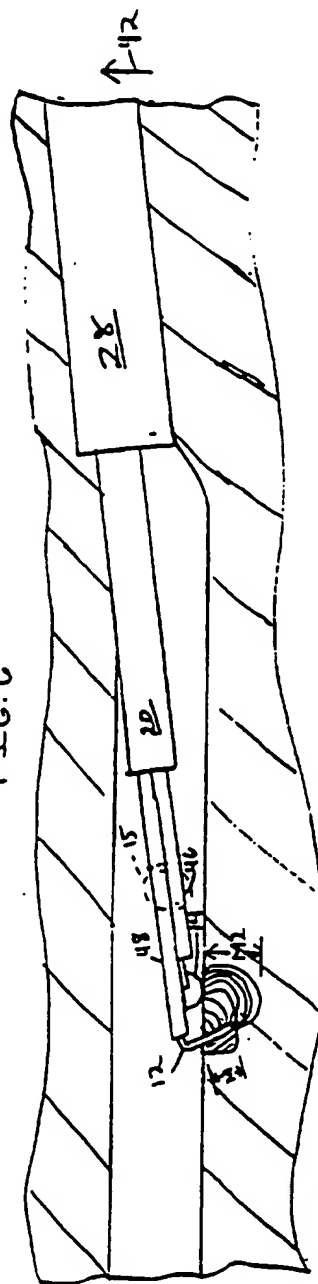
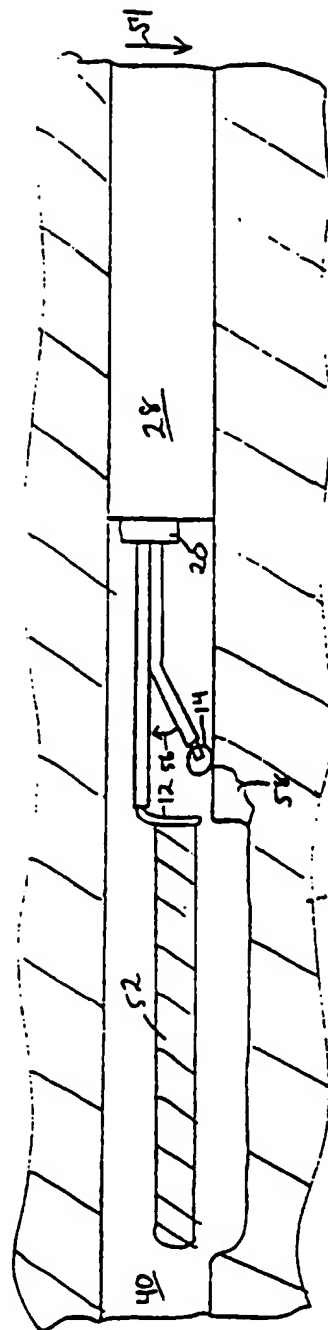
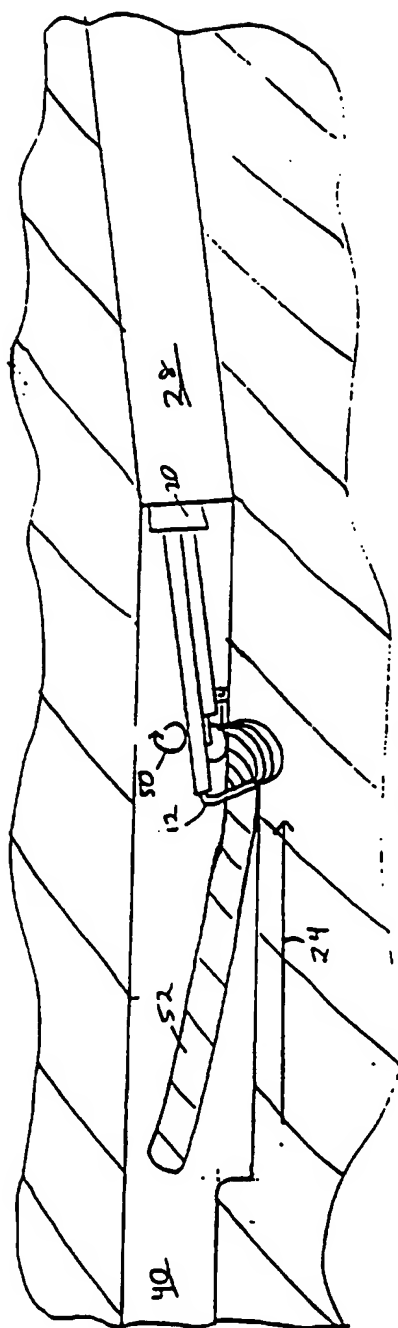
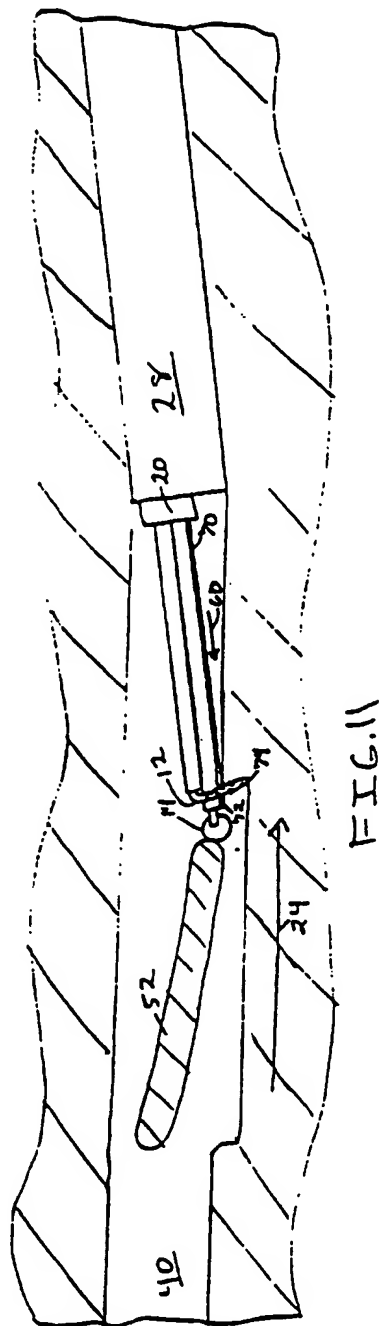
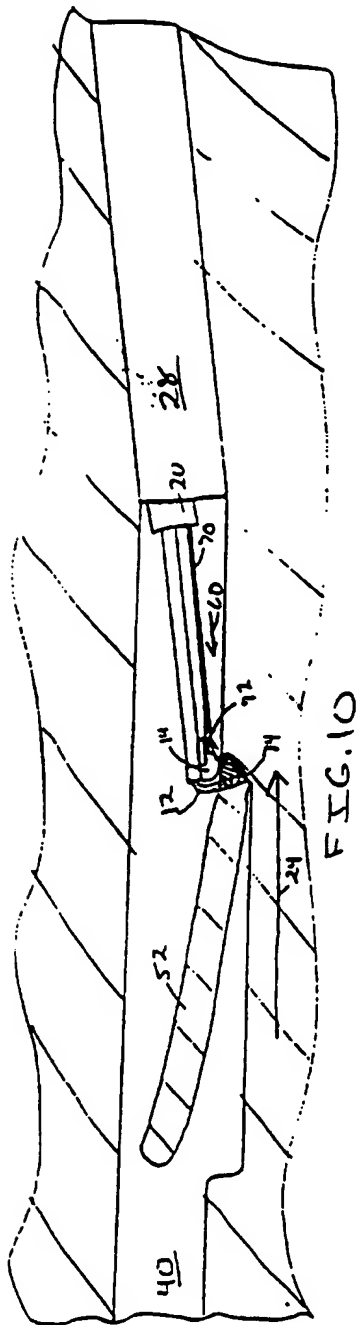


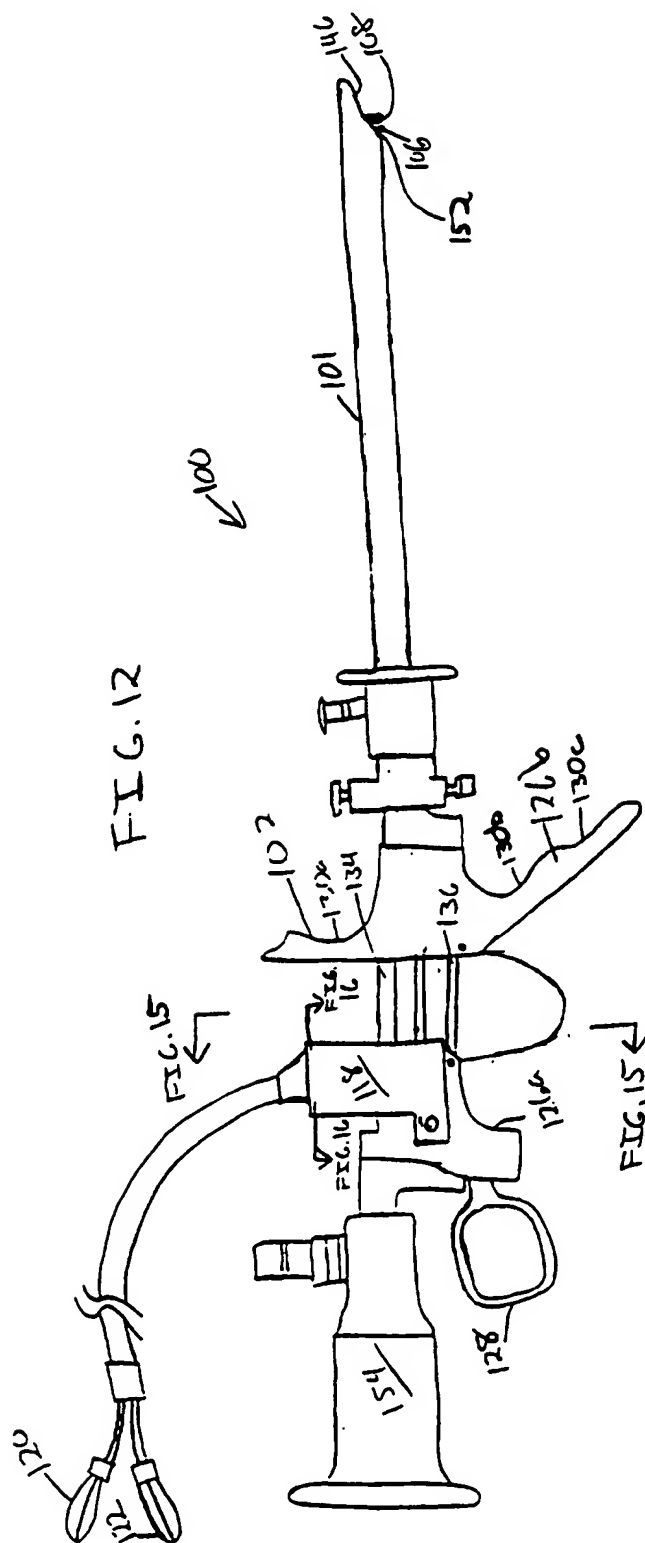
FIG. 7



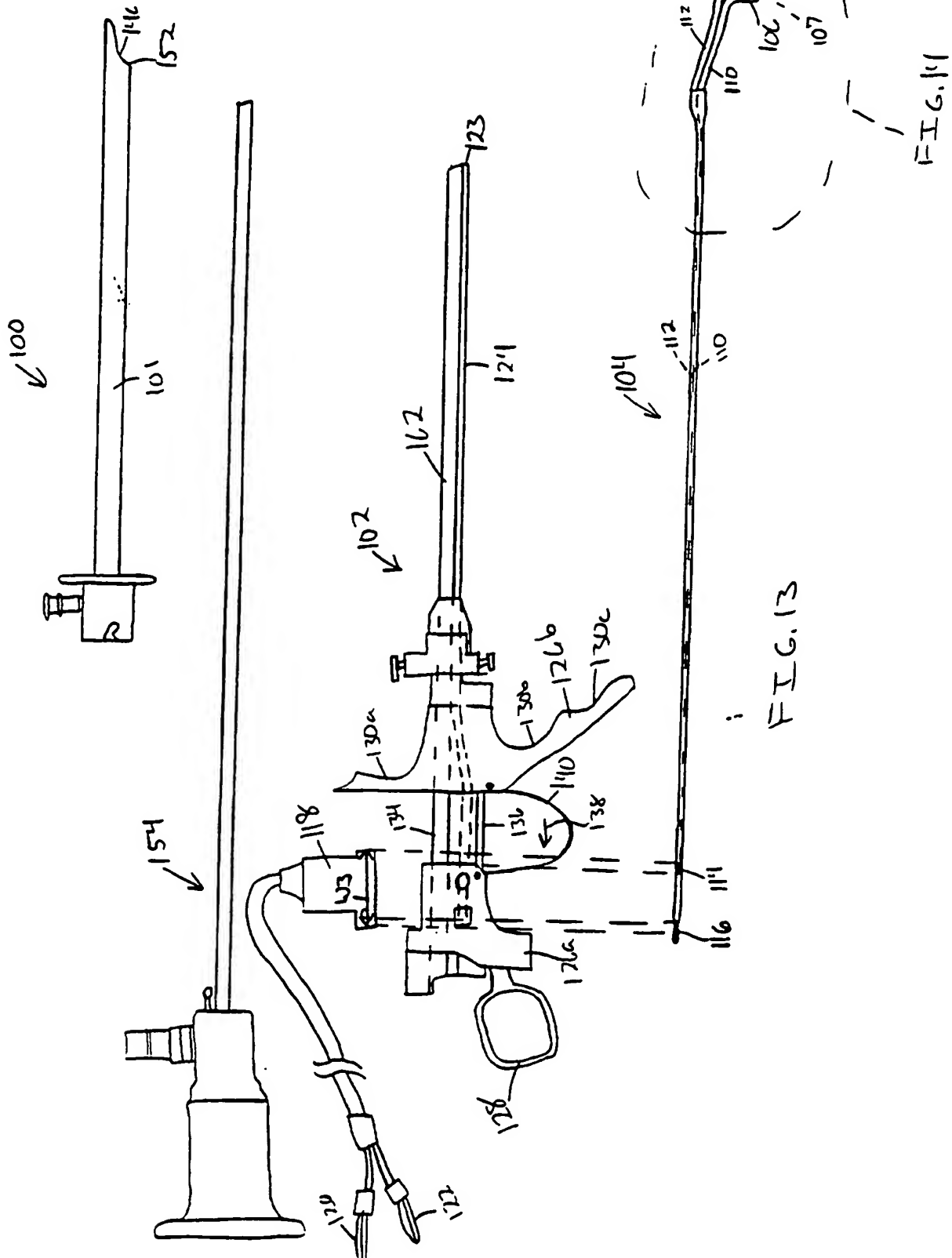
08 / 15



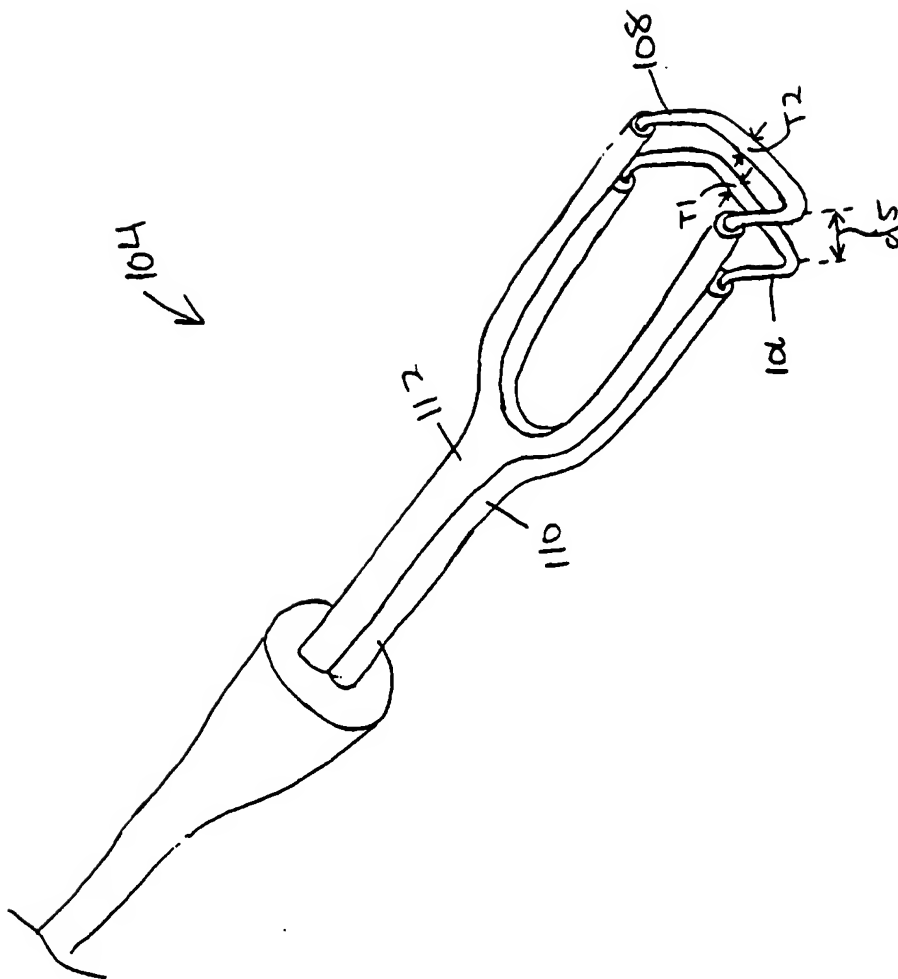
09 / 15



10 / 15



11 / 15



FI 6.14

12 / 15

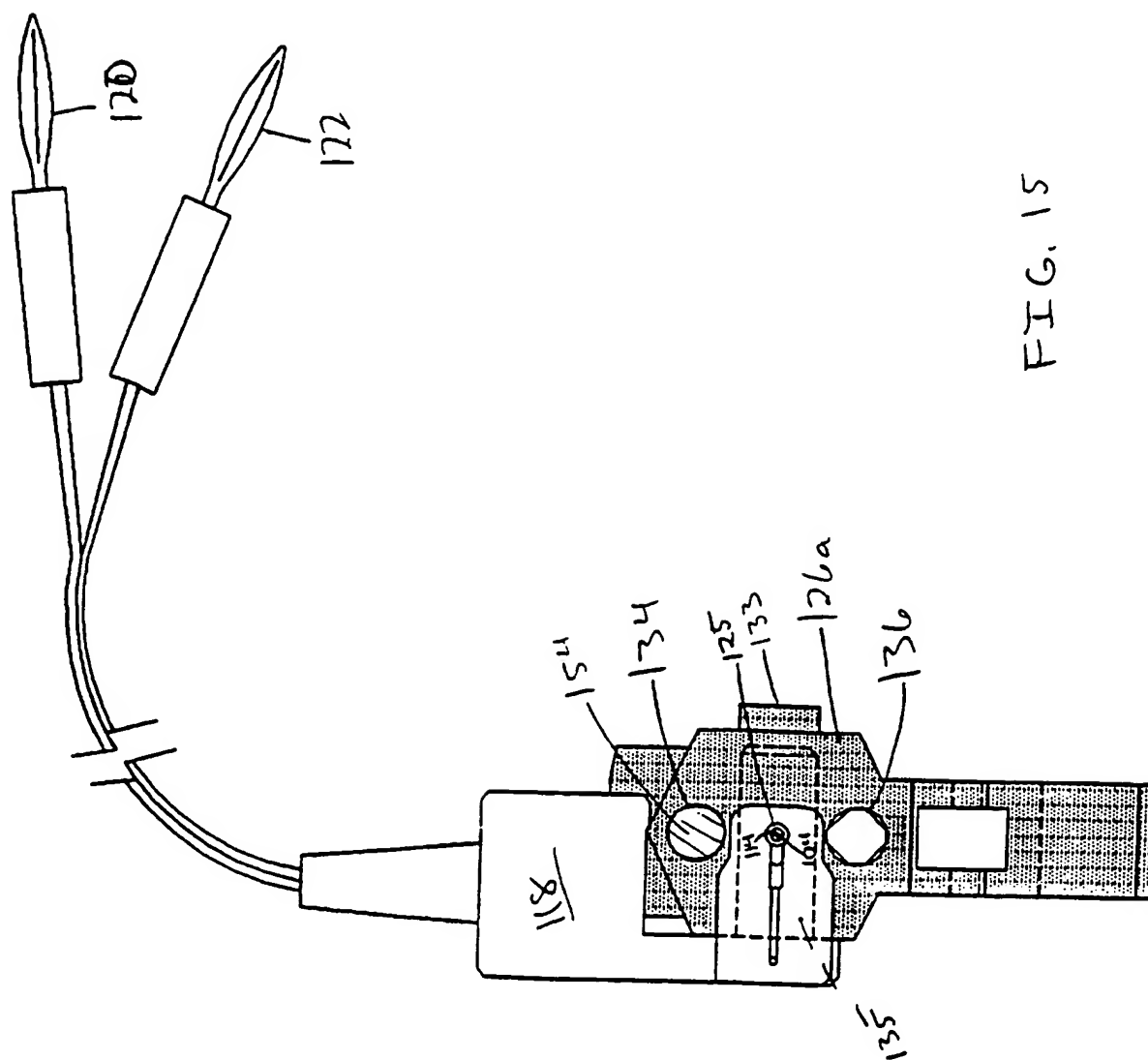


FIG. 15

FIG. 17a

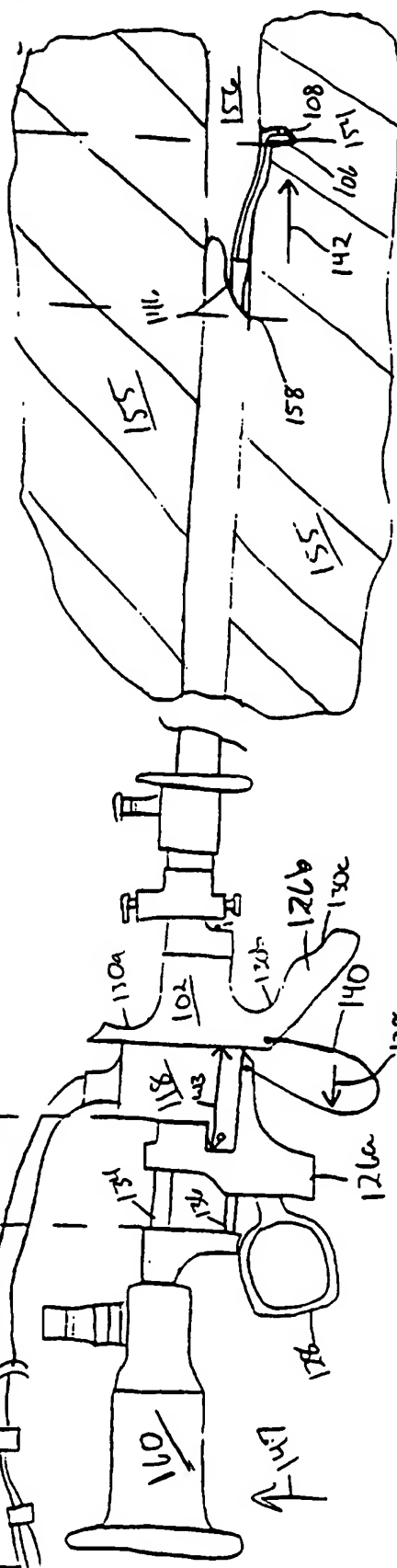
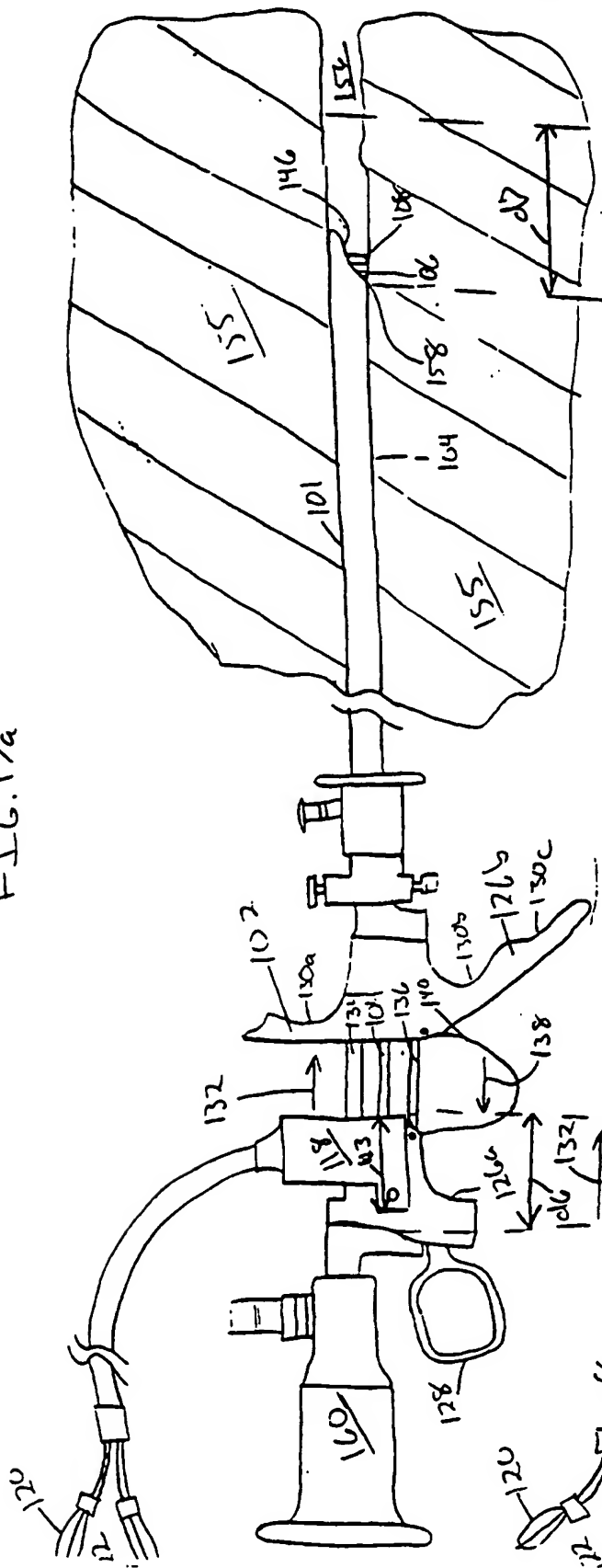
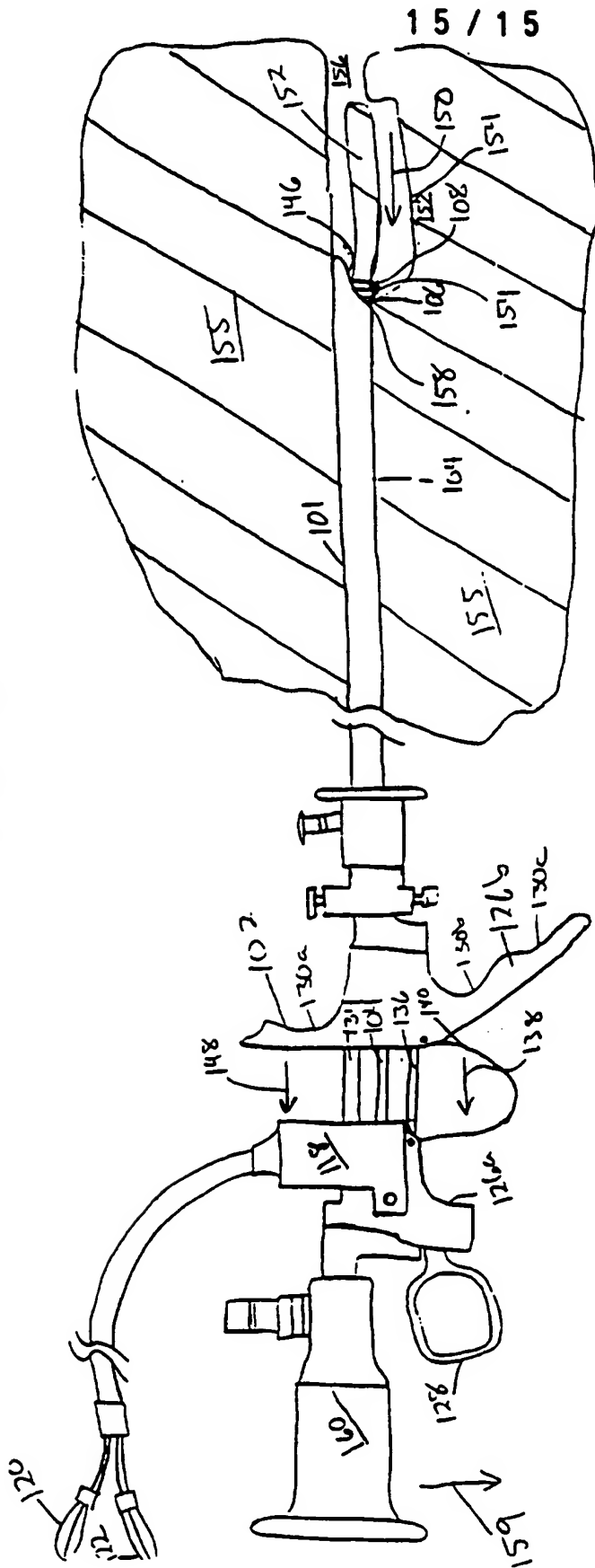


FIG. 17b

FIG. 17c



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/01331

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/39
US CL :606/46, 48, 50

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/45, 46, 48-50

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 2,056,377 (F. C. WAPPLER) 06 October 1936, see entire document.	8, 9 ----- 21-24
X	US, A, 4,060,087 (HILTEBRANDT ET AL.) 29 November 1977, see entire document	4, 5
X --- Y	US, A, 4,116,198 (ROOS) 26 September 1978, see entire document.	1-11, 13-20, 25-27, 32 36- 41, 45, 47 ----- 12, 21-24
Y	US, A, 5,007,908 (RYDELL) 16 April 1991, see column 3 lines 35-57.	11-20, 24, 39

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be part of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 07 MARCH 1996	Date of mailing of the international search report 06 MAY 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer LEE S. COHEN <i>Jon Hill</i> Telephone No. (703) 308-2998

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/01331

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 5,047,027 (RYDELL) 10 September 1991, see entire document.	1-6, 8, 9, 25-53, 36-38, 40-42, 45, 47 ----- 11-24, 39
A, P	US, A, 5,484,435 (FLEENOR ET AL.) 16 January 1996, see entire document.	1-47

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.